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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,555	07/07/2003	Howard B. Gamper	44685-0001 CT1	9045

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,555

Applicant(s)

GAMPER ET AL.

Examiner

Richard Schnizer, Ph. D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-35 and 62-66, drawn to a binary hybrid mutational vector, classified in class 536, subclass 23.1.
- II. Claims 36-40, drawn to a set of oligonucleobases comprising an oligonucleobase targeting strand and a plurality of unique oligonucleobase mutator strands, classified in class 536, subclass 23.1.
- III. Claims 41-48, 57, and 67-71, drawn to methods of altering gene sequences in a non-plant cell, classified for example in class 435, subclass 455.
- IV. Claims 41-49, 57 and 67-71, drawn to methods of altering gene sequences in a plant cell, classified in class 435, subclass 468.
- V. Claims 50-56 and 67-71, drawn to methods of treating a genetic disease, classified in class 514, subclass 44.
- VI. Claim 58, drawn to a method of making a transgenic animal by delivering a hybrid binary mutation vector to a gamete, fusing that gamete with another gamete to form a zygote, and allowing the zygote to develop into an animal, classified in class 800, subclass 21.

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VII. Claim 59, drawn to a method of making a transgenic animal by delivering a binary hybrid mutational vector to a zygote and allowing the zygote to develop into an animal, classified in class 800, subclass 21.

VIII. Claims 60 and 61, drawn to methods of making a transgenic plant, classified in class 800, subclass 278.

Claims 41-48 and 57 are generic to a plurality of patentably distinct inventions set forth in groups III and IV. Claims 67-71 are generic to a plurality of patentably distinct inventions set forth in groups III-V. Should Applicant elect any of these groups, the claims will be examined only to the extent that they are defined by the elected group.

The inventions are distinct, each from the other because of the following reasons:

Group I is related to group II because the oligonucleobases of group II can be used to form a binary hybrid mutational vector of group I. The inventions are distinct because group II requires a collection of unique, structurally and functionally distinct mutator strands, whereas group I allows for only one mutator strand. The inventive concept of group II is a group of vectors which differ in structure and function, whereas the vector of group I has only a single structure and function.

Groups III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions cannot be used together because one results in the formation of a transgenic plant and the other results in the formation of a transgenic

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animal. The method steps of one method cannot be used to arrive at the results of the other method.

Groups I and II are related to groups III-VIII as products to processes for use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case these compositions could be used in materially different processes such as methods to alter either plant or animal cells. Such processes are materially different and patentably distinct for the reasons given in the preceding paragraph.

Group III is unrelated to group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the plant of group VIII cannot be used in, or made by, the method of group III. As such the inventions are not disclosed as capable of use together and have different functions and effects.

Group IV is unrelated to groups V-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the animals of groups VI and VII cannot be used in, or made by, the method of group IV. As such the inventions are not disclosed as capable of use

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together and have different functions and effects. Furthermore, the specification does not disclose use of the treatment of any plant genetic disease, so the method of group IV cannot have been disclosed in the treatment of any plant genetic disease.

Group V is unrelated to groups VI -VIII. Group V requires the ex vivo genetic modification of cells taken from a diseased subject, and the return those cells to the subject. Groups VI and VII require genetic modification of either a gamete, or a zygote, and the subsequent formation of an individual. Group VIII requires the production of a plant. Clearly the methods are not disclosed as capable of together, and have different functions and effects.

Group III is distinct from the methods of groups V-VII, because the method steps of group III may be used in each of these methods, and the method of group V is patentably distinct from the methods of groups VI and VII, for the reasons given above. Furthermore the method of group III does not require any of the method steps required to make the transgenic animals of groups VI and VII thus the inventions require non-coextensive searches.

Group IV is distinct from group VIII because although the method steps of group IV may be used in the process of group VIII, it does not require the production of a transgenic plant, thus the searches are not coextensive.

Groups VI and VII are unrelated to group VIII. The methods of groups VI and VII lead to the production of a transgenic animal, whereas group VIII leads to a transgenic

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plant. Thus the methods require different steps and reagents, are not disclosed as capable of use together, and have different functions and effects.

Groups VI and VII are related to the extent that they both result in the production of a transgenic animal. However the methods are distinct because they require different steps which are not disclosed as practiced together in one method. For example, the specification does not contemplate first genetically modifying a gamete, using it to form a zygote, and then genetically modifying the zygote.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-

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272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

A handwritten signature in black ink, appearing to read 'Richard Schnizer', with a stylized flourish at the end.

Richard Schnizer, Ph.D.